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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,769	10/25/2000	Darwin J Prockop	9598-101U2(99-0356)	4022

7590 02/26/2003

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,769

Applicant(s)

PROCKOP ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's response and amendments filed 12-12-02 have been received and entered.
2. Claims 30 and 37-41 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
3. This application contains claims 30 and 37-41 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claims 1-29 and 31-36 are under consideration.
5. Applicants request for Revocation and power of attorney by the assignee is acknowledged and entered.
6. The 112 second paragraph rejections have been withdrawn in view of applicants' amendments.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-21 are rejected under 35 U.S.C. 102(b) as anticipated by Bruder et al (Journal of Cellular Biochemistry 64:278-294, 1997) for reasons of record set forth in the previous office action of 6-5-02.

Response to Arguments

Applicant's arguments filed 12-12-02 have been fully considered but they are not persuasive. Applicants' arguments that Bruder does not teach each and every element of claims 1-21 are not persuasive. The only two embodiments of the claimed invention are- isolated human marrow stromal cells that have density of less than 50 cells per square centimeter of growth surface and incubating the growth surface in the presence of growth promoting conditions. Applicants' arguments regarding the definition of the human marrow stromal cells in the specification, it is noted that claims are given broadest possible interpretation and the description is not read into claim language when considering the claimed invention.

Bruder et al teaches isolated bone marrow cells that have approximately 1 marrow stromal cell in 10^5 cells, which represents 100 cells in a 60 cm² dish. Accordingly, the art of Bruder et al would meet the limitations of the claimed invention.

9. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznetsov et al (Journal of Bone and Mineral Research 12:1335-1347, 1997) for reasons of record set forth in the previous office action of 6-5-02.

Response to Arguments

Applicant's arguments filed 12-12-02 have been fully considered but they are not persuasive. As noted in the previous paragraph (#7), Applicants' arguments that the reference does not teach each and every element of claims 1-21 are not persuasive. The only two embodiments of the claimed invention are - isolated human marrow stromal cells that have density of less than 50 cells per square centimeter of growth surface and incubating the growth surface in the presence of growth promoting conditions. Applicants' arguments regarding the definition of the human marrow stromal cells in the specification, it is noted that claims are given broadest possible interpretation and the description is not read into claim language when considering the claimed invention. Kuznetsov et al teaches single colony derived strains of human marrow stromal fibroblasts (HMSF) cells. Second paragraph in the left column of page 1337 teaches the method of singly colony derived HMSF which comprising plating cells at $.14-14 \times 10^3$ cells/cm² or $0.007 - 3.5 \times 10^3$ cells/cm². The art also teaches multiple passaging and cell culture medium comprised fetal bovine serum (see the last paragraph in the right column on page 1336).

10. The rejected of claims 1-21 under 35 U.S.C. 102(a) as being anticipated by DiGirolamo et al (British Journal of Haematology 107:275-281, 1999) has been withdrawn in view of Applicants arguments and evidence that the journal was dated November 1999 and that the priority document was filed October 1999.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuznetsov et al (Journal of Bone and Mineral Research 12:1335-1347, 1997) in view of Azizi et al (Proc. Natl. Acad. Sci. USA 95:3908-3913, 1998) for reasons of record set forth in the previous office action of 6-5-02.

Response to Arguments

Applicant's arguments filed 12-12-02 have been fully considered but they are not persuasive. Applicants' arguments that Bruder does not teach each and every element of claims 1-21 are not persuasive. The only two embodiments of the claimed invention are- isolated human marrow stromal cells that have density of less than 50 cells per square centimeter of growth surface and incubating the growth surface in the presence of growth promoting conditions. Applicants' arguments regarding the definition of the human marrow stromal cells in the specification, it is noted that claims are given broadest possible interpretation and the description is not read into claim language when considering the claimed invention. Kuznetsov et al teaches single colony derived strains of human marrow stromal fibroblasts (HMSF) cells. Second paragraph in the left column of page 1337 teaches the method of singly colony derived HMSF which comprising plating cells at $.14-14 \times 10^3$ cells/cm² or $0.007 - 3.5 \times 10^3$ cells/cm². Therefore, the issue of Kuznetsov et al not teaching all the limitations is not persuasive. Regarding the issue of combining and reasonable expectation of success, it is noted that adding PDGF-AA to the culture medium would have been obvious due to the effect of PDGF-AA on the growth rate of marrow stromal cells and applicants have not provided any evidence as to why an artisan would not have had reasonable expectation of success. While the brain and bone, applicants do not provide any evidence that their growth requirements pertaining to PDGF are different.

13. Claims 1, 24-29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuznetsov et al and Azizi et al as applied to claims 22-23 above, and further in view of Greenberger et al (US Patent No 5,766,950, 6-16-1998) and

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Prockop (Science 276:71-74, 1997) for reasons of record set forth in the previous office action of 6-5-02.

Response to Arguments

Applicant's arguments filed 12-12-02 have been fully considered but they are not persuasive. Applicants' arguments that Bruder does not teach each and every element of claims 1-21 are not persuasive. The only two embodiments of the claimed invention are- isolated human marrow stromal cells that have density of less than 50 cells per square centimeter of growth surface and incubating the growth surface in the presence of growth promoting conditions. Applicants' arguments regarding the definition of the human marrow stromal cells in the specification, it is noted that claims are given broadest possible interpretation and the description is not read into claim language when considering the claimed invention. Kuznetsov et al teaches single colony derived strains of human marrow stromal fibroblasts (HMSF) cells. Second paragraph in the left column of page 1337 teaches the method of singly colony derived HMSF which comprising plating cells at $.14-14 \times 10^3$ cells/cm² or $0.007 - 3.5 \times 10^3$ cells/cm². Therefore, the issue of Kuznetsov et al not teaching all the limitations is not persuasive. Regarding the issue of combining and reasonable expectation of success, it is noted that adding growth factors or any other culture condition has nothing to do with the source of the marrow cells and conditions could be applied to cells of different sources. Applicants' do not provide any evidence as to why an artisan would not have had reasonable expectation of success in combining the conditions because an artisan of ordinary skill in the art will have the conditions for the marrow stromal cells from different sources and in fact Prockop article reviews overall state of the art of stem cells and therefore, all the different types of tissues that can be derived from marrow stromal cells are discussed in this article (see the entire article).

14. No claim is allowed.

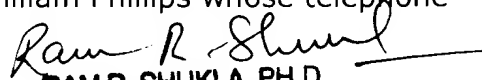
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to **§ 1.121(c)**. For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.


RAM R. SHUKLA, PH.D
PATENT EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632